MAY 16 2013

510(k) Summary

Elite-i (RA) Dual Lumen Catheter, Elite-i (Bi) Dual Lumen Catheter and Elite-i (BiX) Dual Lumen Catheter - K130639

Prepared: May 13, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information

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Summary Date: May 13, 2013

II. Device Name

Proprietary:	Elite-i (RA) Dual Lumen Catheter
	Elite-i (Bi) Dual Lumen Catheter
	Elite-i (BiX) Dual Lumen Catheter
Common:	Cardiopulmonary Bypass Vascular Catheter
Classification:	Class II
Product Code:	DWF
CFR Section:	21 CFR 870.4210

III. Predicate Device:

Predicate Device: Avalon Elite® Bi-Caval Dual Lumen Catheter - K081820

IV. Device Description

The Elite-i (RA) Dual Lumen (short lengths), Elite-i (Bi) Dual Lumen (standard) and Elite-i (BiX) Dual Lumen (extra-long lengths) are wire-reinforced catheters with a one-piece, dual lumen construction. The Dual Lumen Catheter is a single catheter with two separate lumens within the catheter body to collect and to return the blood. The product is offered in a range of sizes to address varying patient size requirements.

The catheters are intended to be inserted via the internal jugular vein into the superior vena cava, the right atrium and the inferior vena cava (except for the short lengths which only reach the right atrium). The catheter's dual lumen construction allows for both venous drainage and reinfusion of blood during extracorporeal life support procedures. The catheters are designed for use by physicians trained in and experienced with venous catheterization and extracorporeal life support in a hospital setting.

Each catheter is supplied with a tapered tip introducer to facilitate placement into the vasculature using a guide wire and following normal access techniques. In addition to the standard introducer, the Elite-i (RA) Dual Lumen Catheter (short lengths) is supplied with an extra, blunt tip introducer to accommodate user preference for placement into the right atrium. Both the catheter and introducers are radiopaque and include depth or location marks. The standard introducer is designed to follow a prepositioned standard 0.038" (0.97 mm) guide wire (which is not included). The blunt tip introducers do not require or accommodate a guide wire.

The device is supplied sterile and non-pryogenic in a peel pouch and carton. It is intended for single use.

V. Intended Use

The intended use of the dual lumen catheters remains the same as the predicate device.

The Elite-i Dual Lumen Catheter is intended for use as a single catheter for both venous drainage and reinfusion of blood via the internal jugular vein during extracorporeal life support procedures.

The catheters are intended for use by physicians trained and experienced with venous catheterization and extracorporeal life support which are both done in a hospital setting.

VI. Comparison of Technological Characteristics to Predicate Device

The Elite-i (RA) Dual Lumen Catheters and Elite-i (BiX) Dual Lumen Catheters all utilize the same technological characteristics (design and materials) as the original Bi-Caval Dual Lumen Catheter. The Bi-Caval Catheter line is simply being expanded to include a short version for users who prefer to only access the right atrium and not the inferior vena cava and an extra-long version for those patients whose anatomy requires extra length to access the inferior vena cava adequately.

Embedded, radiopaque tantalum markers are being added to the drainage and infusion ports on all catheter models to enhance radiographic visualization of the catheters. To accommodate the markers, the basket (where the infusion and drainage ports are located) configuration has been slightly modified. For the Elite-i (RA) Dual Lumen Catheter, the hole placement on the catheter has been slightly modified to accommodate placement in the right atrium as opposed to the inferior vena cava. There is a small modification to the hole configuration for the extra-long Elite-i (BiX) Dual Lumen

Catheters. Flow curves for the modified devices will be consistent with the flow-curves of the predicate devices.

A blunt tipped introducer is being added to the short length catheters. This introducer is made from the same material and design as the existing taper tipped introducer. The tip is blunted and closed rather than tapered and open based on customer preference during placement in the right atrium.

Color is being added to the previously clear hemostasis caps (blue for drainage and red for infusion) to address customer and marketing preference. These are non-patient contact parts. However, biocompatibility was confirmed to be acceptable.

VII. Nonclinical Data

Substantial equivalence testing performed and presented in the original Avalon Elite® Bi-Caval Dual Lumen Catheter 510(k) is applicable for the devices included in this submission. These tests included Pressure/Burst, Simulated Use, Kink Resistance, Tensile Strength, Flow Characteristics, Hemolysis and Biocompatibility.

The modified devices were subjected to additional testing based on the Risk Analysis performed relative to the modifications made to the design. Additional testing included:

- Flow curves for the new configurations
- Verification of Biocompatibility for the colored caps and tantalum dots
- Verification of Sterilization for blunt tipped introducers and modified lengths
- Design verification of spring and reinforcement modifications including kink resistance and tensile strength testing.

VIII. Clinical Data

Clinical results were not submitted to support substantial equivalence.

IX. Conclusions

The intended use of the modified Elite-i Dual Lumen Catheters is identical to the previously cleared Avalon Elite® Bi-Caval Dual Lumen Catheters. The design and materials are also substantially the same. The modified catheters are equivalent to the predicate devices in all key areas of features and performance that affect safety and effectiveness based on a Risk Assessment of the modifications made. Therefore, the Elite-i (RA) Dual Lumen Catheters (short lengths) and the Elite-i (BiX) Dual Lumen Catheters (extra-long length) are substantially equivalent to the predicate device, the Avalon Elite® Bi-Caval Dual Lumen Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2013

Maquet Cardiopulmonary AG
C/O Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Neue Rottenburger Strasse 37
72379 Hechingen
Germany

Re: K130639
Trade/Device Name: Elite-I (Bi 100XX; RA 400XX; BiX 300XX) Dual Lumen Catheters
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 30, 2013
Received: May 2, 2013

Dear Ms. Katrin Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130639

Device Name: ELITE-i Dual Lumen Catheter Family **(ELITE-i (Bi) Dual Lumen Catheter, ELITE-i (RA) Dual Lumen Catheter, ELITE-i (BiX) Dual Lumen Catheter)**

Indications for Use: The ELITE-i Dual Lumen Catheter is indicated for use as a single catheter for both venous drainage and reinfusion of blood via the internal jugular vein during extracorporeal life support procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner